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10/762,931

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David Louis Heiner

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09/24/2009

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EXAMINER

HYUN, PAUL SANG HWA

ART UNIT

PAPER NUMBER

1797

NOTIFICATION DATE

DELIVERY MODE

09/24/2009

ELECTRONIC

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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|                              |                                      |                                      |  |
|------------------------------|--------------------------------------|--------------------------------------|--|
| <b>Office Action Summary</b> | <b>Application No.</b><br>10/762,931 | <b>Applicant(s)</b><br>HEINER ET AL. |  |
|                              | <b>Examiner</b><br>PAUL S. HYUN      | <b>Art Unit</b><br>1797              |  |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 03 June 2009.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-19 and 29-38 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-19 and 29-38 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)          | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____                                      |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)          | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____  | 6) <input type="checkbox"/> Other: _____                          |

### **DETAILED ACTION**

The Remarks filed by Applicant on June 3, 2009 has been acknowledged. Applicant's argument that the effective filing date of the application predates the Hartwich et al. reference (US 2003/0035109 A1) cited in the rejections has been fully considered and it is persuasive. Consequently, all rejections cited in the previous Office action have been withdrawn.

#### ***Claim Rejections - 35 USC § 103***

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claims **1-3, 6-10, 13-16, 18, 19 and 29-38** are rejected under 35 U.S.C. 103(a) as being unpatentable over Balch (US 6,083,763) in view of VanBrunt et al. (US 2004/0067164 A1).

Balch discloses an automated molecular analyzer (see Figs. 1 and 9). The analyzer can be used to conduct nucleotide synthesis (see lines 25-45, col. 21). The analyzer comprises a microplate comprising an array of wells (see lines 40-50, col. 4), a dispensing system for delivering reagents to the wells of the microplate (see lines 60-63, col. 5 and claim 1), a light source (e.g. UV lamp, laser) pivotally mounted on one side of a viewing window for exciting the contents of the wells (see lines 35-40, col. 28), a CCD camera positioned beneath the viewing window to obtain images of the wells (see lines 14-50, col. 4), and a software program for providing automated filtering, thresholding, labeling, statistical analysis and quantitative graphical display of each well within seconds (see lines 25-34, col. 6). Because the software program produces

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quantitative graphical display of each well and performs thresholding, it is evident that the software program determines a value associated with the extent of the reaction in each well and it is capable of monitoring the progress of the reaction in each well. The analyzer disclosed by Balch differs from the claimed invention in that Balch does not disclose a dispenser that is configured to discontinue dispensing of reagents to wells where a reaction is not taking place. In addition, Balch does not disclose an aspiration means.

VanBrunt et al. disclose an apparatus for conducting automated assay. The apparatus comprises an array of fluid vessels, a dispensing system that can also aspirate fluids (see (0064)), an optical detector (see [0069]) for monitoring the progress of reactions occurring in the fluid vessels, and a system for processing the output of the detector to determine the subsequent processing step (see Abstract and [0095]). The apparatus is configured such that in the event that the detector does not detect a reaction occurring in a vessel, further processing of that fluid vessel is aborted (see [0095]). In light of the disclosure of VanBrunt et al., it would have been obvious to one of ordinary skill in the art to configure the dispenser disclosed by Balch such that it stops delivering reagents to wells that are not exhibiting any reactions. Such modification would save time and cost. It also would have been obvious to one of ordinary skill in the art to provide the Balch system with an aspirating means as taught by VanBrunt et al. so that fluids from the vessels can be transferred to another vessel.

With respect to claim 10, although Balch does not explicitly disclose that the analyzer can write the data derived by the software program to a data storage location,

it would have been obvious, if not apparent, to enable the analyzer to do so to enable one to access the data at a later time. It is well known in the art that computers are capable of saving data to a storage device.

With respect to claims 30-38, the claims attempt to further limit the invention by reciting method steps that the invention is capable of conducting. It should be noted that a system capable of conducting the claimed method steps is deemed to be within the scope of the claims regardless of whether the system actually conducts the claimed method steps. In this case, the scanning system disclosed by VanBrunt et al. comprises a processor capable of accomplishing the method steps recited in claims 30-38.

Claims **4, 5 and 17** are rejected under 35 U.S.C. 103(a) as being unpatentable over Balch in view of VanBrunt et al. as applied to claims 1-3, 6-10, 13-16, 18, 19 and 29-38 above, and further in view of Vo Dinh et al. (US 6,448,064 B1).

Neither Balch nor VanBrunt et al. disclose the use of LED arrays to excite the sample.

Vo Dinh et al. disclose a biochip for conducting reactions. The biochip comprises an array of reaction sites 143 and a plurality of LED arrays 144, each LED array configured to excite the sample of one reaction site (see Fig. 3 and Example 5, col. 16). In light of the disclosure of Vo Dinh et al., it would have been obvious to use LEDs to excite the sample disclosed by Balch since LEDs are common and cheaper than laser. It also would have been obvious to provide a light source for each reaction site of the

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modified Balch analyzer. The use of a plurality of light sources would increase efficiency.

Claim **11** is rejected under 35 U.S.C. 103(a) as being unpatentable over Balch in view of VanBrunt et al. as applied to claims 1-3, 6-10, 13-16, 18, 19 and 29-38 above, and further in view of Eyster et al. (US 2003/0207441 A1).

Neither Balch nor VanBrunt et al. disclose a computer system that generates a warning message based on the extent of the reaction occurring within the reaction site of an array.

Eyster et al. disclose an apparatus for measuring the concentration of an analyte of interest. The apparatus comprises an array of sample, a light source for inducing a signal from the array of sample, a CCD camera for producing an image of the signal (see [0077]), and a means for displaying a message if the measurement values derived from the wells deviate from a control value (see [0102]). In light of the disclosure of Eyster et al., it would have been obvious to one of ordinary skill in the art to provide the modified Balch analyzer with a means that can generate a message if measurement values derived from the wells deviate from a control value so that the user can determine the source of the deviation.

Claim **12** is rejected under 35 U.S.C. 103(a) as being unpatentable over Balch in view of VanBrunt et al. as applied to claims 1-3, 6-10, 13-16, 18, 19 and 29-38 above, and further in view of Dower et al. (US 5,639,603).

Neither Balch nor VanBrunt et al. disclose a centrifuge rotor associated with the liquid removing device.

Dower et al. disclose an automated apparatus for conducting synthesis reactions in a microplate wherein the apparatus comprises an aspirator for removing fluid from the wells of the microplate. The apparatus can further comprise a centrifuge for separating the contents of a reaction vessel prior to aspirating those contents (see lines 42-59, col. 42). In light of the disclosure of Dower et al., it would have been obvious to one of ordinary skill in the art to provide a centrifuge to the modified Balch analyzer so that the contents of the wells of the microplate can be separated prior to removing the content of interest from the wells.

Claims **1-4, 6-8 and 29-33** are rejected under 35 U.S.C. 103(a) as being unpatentable over Balch in view of Hartwich et al. (WO 01/69210 A1).

As discussed above, Balch discloses an automated molecular analyzer (see Figs. 1 and 9). The analyzer disclosed by Balch differs from the claimed invention in that Balch does not disclose a dispenser that is configured to discontinue dispensing of reagents to wells where a reaction is not taking place.

Hartwich et al. disclose an automated system for carrying out reactions in an array format (e.g. microplate). The system comprises a supply system (e.g. pipette), and a scanning system for detecting the existence of a reaction in the wells of the array. If the scanning system does not detect a reaction in a well belonging to a group of wells designated for conducting a specific reaction, further processing of the rest of the wells

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belonging to that group is discontinued to optimize efficiency and cost. In light of the disclosure of Hartwich et al., it would have been obvious to one ordinary skill in the art to configure the dispenser disclosed by Balch such that it stops delivering reagents to wells that are not exhibiting any reactions. Such modification would save time and cost.

With respect to claim 4, Balch does not disclose the use of an array of LEDs as the light source. However, Hartwich et al. disclose the use of an array of LEDs to excite samples in the wells (see claim 4). In light of the disclosure, it would have been obvious to use an array of LEDs as the light source in the system disclosed by Balch since diodes are much cheaper than laser.

With respect to claims 30-33, the claims attempt to further limit the invention by reciting method steps that the invention is capable of conducting. It should be noted that a system capable of conducting the claimed method steps is deemed to be within the scope of the claims regardless of whether the system actually conducts the claimed method steps. In this case, the scanning system disclosed by Hartwich et al. comprises a processor capable of accomplishing the method steps recited in claims 30-33.

Claim **5** is rejected under 35 U.S.C. 103(a) as being unpatentable over Balch in view of Hartwich et al. as applied to claims 1-4, 6-8 and 29-33, and further in view of Vo Dinh et al.

Neither Balch nor Hartwich et al. disclose the use of more than one LED array to excite the sample.

Vo Dinh et al. disclose a biochip for conducting reactions. The biochip comprises an array of reaction sites 143 and a plurality of LED arrays 144, each LED array configured to excite the sample of one reaction site (see Fig. 3 and Example 5, col. 16). In light of the disclosure of Vo Dinh et al., it would have been obvious to provide a light source for each reaction site of the modified Balch analyzer. The use of a plurality of light sources would increase efficiency and minimize cost.

Claims **9, 10, 13-16, 18, 19 and 34-38** are rejected under 35 U.S.C. 103(a) as being unpatentable over Balch in view of Hartwich et al. and Becker et al. (US 7,625,061 B1).

As discussed above, Balch discloses an automated molecular analyzer. The analyzer disclosed by Balch differs from the claimed invention in that Balch does not disclose a dispenser that is configured to discontinue dispensing of reagents to wells where a reaction is not taking place. In addition, Balch does not disclose an aspiration means.

With respect to the dispenser that is configured to discontinue dispensing of reagents to wells where a reaction is not taking place, Hartwich et al. disclose such a device as discussed above. In light of the disclosure of Hartwich et al., it would have been obvious to one ordinary skill in the art to configure the dispenser disclosed by Balch such that it stops delivering reagents to wells that are not exhibiting any reactions. Such modification would save time and cost.

With respect to the aspiration means, Beck et al. disclose an automated system for performing polynucleotide synthesis reactions. The system comprises a microplate (see line 55, col. 15), a CCD for obtaining images of the wells of the microplate, a dispensing system, and a device for removing liquids from the wells of the microplate (see lines 36-56, col. 23). The device can transfer the aspirated fluid to another target site or a waste chamber. In light of the disclosure of Becker et al., it would have been obvious to one of ordinary skill in the art to provide the Balch system with a device that can remove fluids from the wells of the microplate to another well or to dispose of it.

With respect to claim 10, although Balch does not explicitly disclose that the analyzer can write the data derived by the software program to a data storage location, it would have been obvious, if not apparent, to enable the analyzer to do so to enable one to access the data at a later time. It is well known in the art that computers are capable of saving data to a storage device.

With respect to claim 16, Balch does not disclose the use of an array of LEDs as the light source. However, Hartwich et al. disclose the use of an array of LEDs to excite samples in the wells (see claim 4). In light of the disclosure, it would have been obvious to use an array of LEDs as the light source in the system disclosed by Balch since diodes are much cheaper than laser.

With respect to claims 35-38, the claims attempt to further limit the claimed invention by reciting method steps that the invention is capable of conducting. It should be noted that a system capable of conducting the claimed method steps is deemed to be within the scope of the claims regardless of whether the system actually conducts

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the claimed method steps. In this case, the scanning system disclosed by Hartwich et al. comprises a processor capable of accomplishing the method steps recited in claims 35-38.

Claim **11** is rejected under 35 U.S.C. 103(a) as being unpatentable over Balch in view of Hartwich et al. and Becker et al. as applied to claims 9, 10, 13-16, 18, 19 and 34-38, and further in view of Eyster et al.

None of Balch, Hartwich et al. and Becker disclose a computer system that generates a warning message based on the extent of the reaction occurring within the reaction site of an array.

Eyster et al. disclose an apparatus for measuring the concentration of an analyte of interest. The apparatus comprises an array of sample, a light source for inducing a signal from the array of sample, a CCD camera for producing an image of the signal (see [0077]), and a means for displaying a message if the measurement values derived from the wells deviate from a control value (see [0102]). In light of the disclosure of Eyster et al., it would have been obvious to one of ordinary skill in the art to provide the modified Balch analyzer with a means that can generate a message if measurement values derived from the wells deviate from a control value so that the user can determine the source of the deviation, whether it be an error in the CCD or the protocol of the experiment.

Claim **12** is rejected under 35 U.S.C. 103(a) as being unpatentable over Balch in view of Hartwich et al. Becker et al. as applied to claims 9, 10, 13-16, 18, 19 and 34-38, and further in view of Dower et al.

None of Balch, Hartwich et al. and Becker et al. disclose a centrifuge rotor associated with the liquid removing device.

Dower et al. disclose an automated apparatus for conducting synthesis reactions in a microplate wherein the apparatus comprises an aspirator for removing fluid from the wells of the microplate. The apparatus can further comprise a centrifuge for separating the contents of a reaction vessel prior to aspirating those contents (see lines 42-59, col. 42). In light of the disclosure of Dower et al., it would have been obvious to one of ordinary skill in the art to provide a centrifuge to the modified Balch analyzer so that the contents of the wells of the microplate can be separated prior to removing fluid from the wells.

Claim **17** is rejected under 35 U.S.C. 103(a) as being unpatentable over Balch in view of Hartwich et al. and Becker as applied to claims 9, 10, 13-16, 18, 19 and 34-38, and further in view of Vo Dinh et al.

None of Balch, Hartwich et al. and Becker disclose the use of more than one LED array to excite the sample.

Vo Dinh et al. disclose a biochip for conducting reactions. The biochip comprises an array of reaction sites 143 and a plurality of LED arrays 144, each LED array configured to excite the sample of one reaction site (see Fig. 3 and Example 5, col. 16).

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In light of the disclosure of Vo Dinh et al., it would have been obvious to provide a light source for each reaction site of the modified Balch analyzer. The use of a plurality of light sources would increase efficiency and minimize cost.

### ***Response to Arguments***

Applicant's arguments with respect to the rejected claims have been fully considered and they are persuasive. Therefore, the rejections have been withdrawn. However, upon further consideration, new grounds of rejection have been made.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to PAUL S. HYUN whose telephone number is (571)272-8559. The examiner can normally be reached on Monday-Friday 8AM-4:30PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jill Warden can be reached on (571)-272-1267. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Paul S Hyun/  
Examiner, Art Unit 1797

/Jill Warden/  
Supervisory Patent Examiner, Art Unit 1797

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